AUG 2 2 2001

K001853

510(k) Summary

General Information

Classification	Class II
Trade Name	SMS-1™ Syringe Management System
Submitter	Medtech Systems, Inc. 4825 Olson Memorial Highway Suite 103 Golden Valley, MN 55422 763-417-0960
Contact	Gary Miller President

Intended Use

The Syringe Management System Model SMS-1 is intended for the safe management of used syringe/hypodermic needle sets. The SMS-1 will automatically separate and disable syringes by removing the needle from the hub and slightly deforming the syringe distal tip. Following disabling, the syringe and needle are dropped into a sealed sharps container for disposal per institutional guidelines.

Predicate Devices

K946735	Sharps Away – Biomedical Waste Systems, Inc.
K925086	Automatic Needle Disconnect (A.N.D.) – Post Medical, Inc.

Device Description

The SMS-1 is a battery powered portable self-contained unit designed to be placed on a table top or cart

The basic SMS-1 unit is about the size of a shoe-box. The exterior housing is molded plastic. A wall mounted charger is used to recharge the battery.

Materials

All materials used in the manufacture of the SMS-1 are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included electrical safety, eletro-magnetic compatibility, syringe processing, receiver operation, leakage, spill and puncture resistance.

Summary of Substantial Equivalence

The SMS-1 Syringe Management System is equivalent to the predicate products from Biomedical Waste Systems and Post Medical. The indications for use, basic overall function, methods of manufacturing, and materials used are substantially equivalent. Medtech Systems believes the SMS-1 is substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Mr. Gary Miller
President
Medtech Systems, Incorporated
4825 Olson Memorial Highway, Suite 103
Golden Valley, Minnesota 55422

Re: K001853
Trade/Device Name: Syringe Management System, Model SMS-1
Regulation Number: 880.5570
Regulatory Class: II
Product Code: FMI
Dated: June 22, 2001
Received: June 26, 2001

Dear Mr. Miller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucenite/for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

REMARK # 11

Indications for Use

510(k) Number (if known):	This application
Device Name:	Syringe Management System Model SMS-1
Indications for Use:	**The Syringe Management System Model SMS-1 is intended for the** disposal of medical syringe/needle sets in health care facilities, ambulances and in home care environments. It is intended to be used for syringes up to 20cc, and needles up to 1 ½ inches in length.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001853

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)